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Ansell Healthcare Products LLC

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

**ANSELL HEALTHCARE PRODUCTS  
LLC,**

**Plaintiff,**

**v.**

**MÖLNLYCKE HEALTH CARE US, LLC,**

**Defendant.**

**CIVIL ACTION NO.**

**COMPLAINT**

**The Parties**

1. Ansell Healthcare Products LLC is a limited liability company organized under the laws of the State of Delaware, with a principal place of business located at 200 Schulz Drive, Red Bank, New Jersey 07701.

2. On information and belief, defendant Mölnlycke Health Care US, LLC is a limited liability company organized under the laws of the State of Delaware, whose registered agent for service of process is The Corporation Trust Company located at Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

### **Jurisdiction and Venue**

3. This is an action for false and/or misleading advertising arising under the laws of the United States, Section 43(a) of the Lanham Act, 15 U.S.C. § 1125. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331.

4. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) and (c).

### **General Averments**

5. Ansell Healthcare Products LLC and its affiliated companies (collectively “Ansell”) are the global market leader in surgical gloves.

6. Mölnlycke Health Care US, LLC (“Mölnlycke”) is a provider of single-use surgical and wound products and services for the health care sector. In recent years, Mölnlycke acquired the Biogel line of surgical gloves which feature gloves made out of natural rubber latex, neoprene and polyisoprene.

7. Consistently high product quality is one of the factors that gives Ansell its leading role in the surgical glove market worldwide. Since Ansell’s surgical gloves are used worldwide, they must conform to the most demanding standards set by any of the approximately 70 countries around the world in which Ansell’s surgical gloves are sold. Ansell achieves this by building quality into the design and manufacture of its gloves instead of just relying on manual rejection of bad gloves at the testing stage. Ansell offers an extensive line of surgical gloves aimed at all sectors of the market which includes gloves made out of natural rubber latex, neoprene and polyisoprene.

8. Quality and safety are very important factors with respect to surgical gloves, and rightly viewed as such by Ansell and by glove purchasers.

9. The AORN Annual Congress is touted to potential exhibitors as “the #1 event for professionals in the surgical arena, offering in-person contact with over 7000 peri-operative professionals, key OR decision-makers and qualified candidates.” For instance, at the 56th AORN Annual Congress in 2009, 2,215 hospitals and facilities were represented. Over 600 companies exhibit at the Annual AORN Congress for purposes of closing sales, showcasing product lines and developing a rapport with health care professionals who are operating room product end-users, decision-makers and purchasers.

10. In an attempt to increase sales of its surgical gloves, Mölnlycke distributed an advertising brochure that made false and misleading claims regarding its Biogel surgical gloves (“the Biogel Brochure”) during the 57th Annual AORN Congress held in Denver, Colorado, from March 13-18, 2010. A true and correct copy of the Biogel Brochure is attached hereto as Exhibit A. Statements in the Biogel Brochure misrepresent the nature, characterization and qualities of not only Mölnlycke’s surgical gloves, but also Ansell’s surgical gloves.

11. In the Biogel Brochure, Mölnlycke states explicitly or implicitly that an In-Use Surgical Glove Failure Rate Comparison Study establishes, *inter alia*, that:

- “Biogel gloves [are] a safer choice for teaching hospitals”;
- “Less-experienced and cyclical healthcare practitioners are better protected with Biogel gloves”;

- “In teaching hospitals, where surgical glove wearers rotate through the surgical environment, non-Biogel gloves, on average, are 11.7 TIMES MORE LIKELY TO FAIL”;
- “Biogel gloves have fewer failures and provide greater safety for those practitioners who are still mastering their techniques”;
- Biogel gloves have a “significantly lower failure rate”;
- Biogel gloves are of “significantly higher quality”;
- There was “a STATISTICALLY SIGNIFICANT REDUCTION IN GLOVE FAILURES when the facilities switched to Biogel gloves ( $p = 0.05$ )”;
- “BIOGEL® GLOVES have statistically FEWER FAILURES than other glove brands”;
- Ansell gloves had “8.6 times more failure” than Biogel gloves;
- “On average, non-Biogel gloves are 4.9 TIMES MORE LIKELY TO FAIL than BIOGEL GLOVES”;
- Mölnlycke’s Biogel surgical gloves provide greater protection against needle sticks than do the surgical gloves of its competitors.

12. These statements are literally false and/or misleading and the cited studies were not sufficiently reliable to permit the conclusions presented in the Biogel Brochure, and even if reliable, do not establish many of the propositions asserted.

13. Mölnlycke has been put on notice of the problems with the Biogel Brochure, has been requested to confirm that it has ceased disseminating the Biogel Brochure and the false and misleading statements made therein, and was requested to provide Ansell with copies of all study materials that purport to support the claims made in the Biogel Brochure. Mölnlycke has completely failed to do so.

14. On information and belief, Mölnlycke's false and misleading advertising and its failure to cease and desist has been willful and intended to damage Ansell and other competitors of Mölnlycke in the surgical glove market.

15. The actions of Mölnlycke have caused irreparable damage to Ansell and will continue to do so if injunctive relief is not granted.

#### **Violation of the Lanham Act**

16. The acts and conduct of Mölnlycke as set forth herein violate the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

17. As a result of the acts and conduct of Mölnlycke as set forth herein, Ansell has suffered damage to its reputation, loss of good will, and may lose sales by reason of customers' concerns regarding the safety and quality of Ansell's gloves caused by Mölnlycke's false and misleading advertising.

18. As a result of the acts and conduct of Mölnlycke as set forth herein, Mölnlycke has derived an unfair economic advantage.

WHEREFORE, Ansell prays for judgment in its favor and against Mölnlycke and the grant of the following relief:

A. Preliminary and permanent injunctive relief precluding any further dissemination or communication of the Biogel Brochure or the false and misleading statements made therein;

B. Mandatory injunctive relief requiring Mölnlycke to (1) prominently place corrective advertising on its website and maintain it there for the next two years; and (2) send hard copies of such corrective advertising to all attendees at the AORN 57th Annual Congress and anyone else shown to have received the Biogel Brochure;

C. Monetary damages sufficient to compensate Ansell for the costs of any studies, tests, and corrective advertising necessary to combat the marketplace effects of Mölnlycke's false and misleading advertising;

D. Monetary damages sufficient to compensate Ansell for lost sales and injury to its business reputation and good will;

E. Reasonable attorneys' fees and costs;

F. Prejudgment interest; and

G. Such other relief as the Court may deem proper and just.

**DEMAND FOR JURY TRIAL**

Ansell hereby demands a trial by jury on any and all claims for which it is appropriate.

DATED: April 7, 2010

s/ Robert A. White

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# ***Exhibit A***



In-Use Surgical Glove Failure Rate  
Comparison Study Reveals:

**THE REAL VALUE OF QUALITY.**

**QUALITY REDUCES RISKS AND COSTS.**

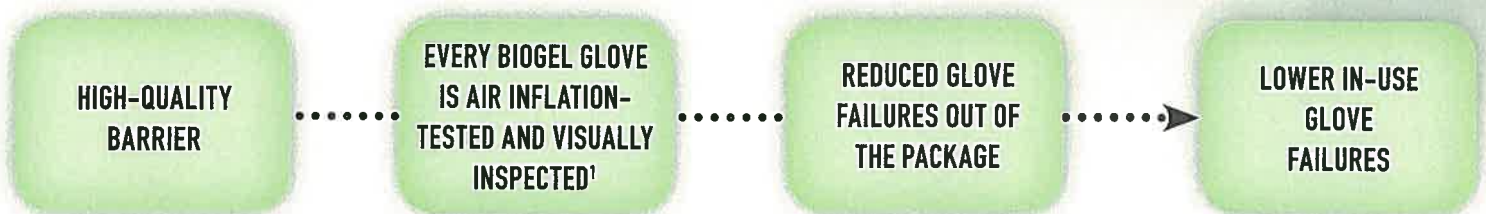


SETTING THE STANDARD IN PROTECTION



## **BIOGEL® GLOVES ARE MORE AFFORDABLE THAN YOU MAY THINK.**

Our goal has always been to make the safest, highest-quality glove to give you superior protection.



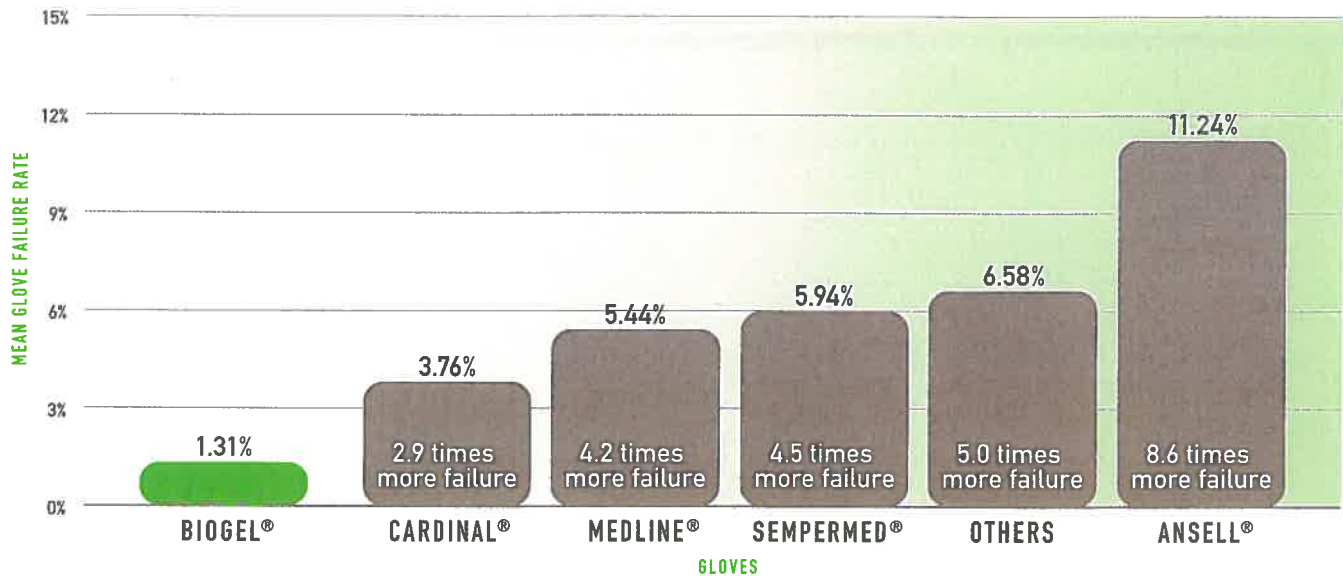
Therefore, with Biogel gloves, you will have lower risk, better protection and the need to purchase fewer gloves².

**CHOOSE BIOGEL GLOVES.** The cost of quality is far lower than you may think.

**Study Results** 4642 gloving events (any time gloves were donned) were measured across all facilities during the study<sup>2</sup>.

## BIOGEL® GLOVES have statistically FEWER FAILURES than other glove brands<sup>2</sup>.

Biogel gloves had a dramatically lower percentage of glove failures ( $p=0.05$ )<sup>2</sup>.



## On average, non-Biogel gloves are 4.9 TIMES MORE LIKELY TO FAIL than BIOGEL GLOVES.

Overall study findings clearly show the advantage of using Biogel gloves. Non-Biogel glove wearers had a 6.3% failure rate. When they switched to Biogel, this rate dramatically decreased to only 1.3%<sup>2</sup>.

FULL STUDY: FAILURE OF NON-BIOGEL VS. BIOGEL WEARERS		GLOVE FAILURE
Non-Biogel	135 of 2129	6.3%
Biogel	33 of 2513	1.3%

A common pattern is shown across all facilities<sup>2</sup>.

GLOVE FAILURES BY FACILITY: NON-BIOGEL VS. BIOGEL WEARERS		GLOVE FAILURE
Hospital A	Non-Biogel	5.8% 17 of 293
	Biogel	0.7% 2 of 275
Hospital B	Non-Biogel	13.8% 17 of 123
	Biogel	2.9% 9 of 307
Hospital C	Non-Biogel	5.3% 30 of 568
	Biogel	1.8% 19 of 1078
Hospital D	Non-Biogel	11.1% 53 of 476
	Biogel	0.2% 1 of 416
Hospital E	Non-Biogel	2.7% 18 of 669
	Biogel	0.5% 2 of 437

Note: Hospitals B and D are teaching hospitals. Hospital E was exclusively polyisoprene glove use.

## **BIOGEL® GLOVES – a SAFER choice for TEACHING HOSPITALS.**

Less-experienced and cyclical healthcare practitioners are better protected with Biogel gloves<sup>2</sup>.

A Johns Hopkins study revealed that medical students are commonly stuck by needles (59%) and many fail to report the injuries to hospital authorities<sup>3</sup>.

This naturally puts students at risk of contracting potentially dangerous blood-borne diseases<sup>3</sup>. Healthcare practitioners in training are working to perfect their technique and knowledge of surgical instrumentation, and because these individuals rotate in and out of surgical services, the need for a safer glove in teaching hospitals has never been more critical.



**In teaching hospitals, where surgical glove wearers rotate through the surgical environment, non-Biogel gloves, on average, are 11.7 TIMES MORE LIKELY TO FAIL<sup>2</sup>.**

The data shows that less-experienced and cyclical non-Biogel glove wearers who only wore gloves for one month of the study had a far higher percentage of glove failures than less-experienced and cyclical Biogel glove wearers.

**Biogel gloves have fewer failures and provide greater safety for those practitioners who are still mastering their technique.**

WEARERS WHO ONLY COMPLETED ONE MONTH OF THE STUDY		GLOVE FAILURE
Non-Biogel		8.2% 43 of 526
Biogel		0.7% 3 of 456

**With proof of Biogel gloves' significantly lower failure rate ...**

Healthcare facilities can use fewer gloves and therefore have the potential to reduce costs.

**With proof of Biogel gloves' significantly higher quality ...**

Healthcare facilities can minimize risk of infection to physicians and staff and therefore increase peace of mind with a safer glove choice.

**The VALUE of BIOGEL GLOVES is CLEAR!**



## In-Use Surgical Glove Failure Rate Comparison Study: Providers see the difference – the risk reduction and the potential savings.

The makers of Biogel® gloves conducted a multi-site In-Use Surgical Glove Failure Rate Comparison Study to determine the incidence of glove failures experienced by practitioners. These failures resulted in practitioners changing their glove(s) in operating rooms.

Glove failures were defined as visible defects identified on opening, tears on donning, punctures in use and other breaches in use<sup>2</sup>.

The objective of the study was to evaluate glove failure rates under in-use conditions during routine surgical procedures.

The study design required the Biogel glove provided to practitioners be similar to their current glove in style (thick or thin, smooth or textured, single-gloved or double-gloved).

Each facility participated for three months.

### Month 1

Existing gloves were used and failures monitored and documented.

### Month 2

Facilities switched to Biogel gloves and no documentation occurred. This gave clinicians and staff a month to acclimate to the new gloves.

### Month 3

Biogel gloves were used and failures monitored and documented.

**The data from Month 1 and Month 3 were compared. Study results demonstrated a statistically significant difference between competitors' gloves and Biogel gloves.**

**This study found a STATISTICALLY SIGNIFICANT REDUCTION IN GLOVE FAILURES when the facilities switched to Biogel gloves ( $p=0.05$ )<sup>2</sup>.**

At Biogel®, our reputation goes hand in hand with the standards we have set over the past 25 years.

#### Freedom from Holes

- Biogel gloves have the best freedom from holes (AQL 0.65)<sup>1</sup>
  - Industry standard test on finished glove packs (D3577-06)
- Every single glove visually inspected for holes<sup>1</sup>
- **Competitors' gloves are typically twice as likely to have a hole<sup>1</sup>**

#### Non-Pyrogenic

- FDA regulations require all implantable surgical devices and IV devices be non-pyrogenic
- Biogel is the only major surgical glove brand with a non-pyrogenic range (pyrogens can result in fever, inflammation and even death)<sup>4</sup>
- **Biogel gloves reduce the potential risk of harmful reactions to pyrogens, which can potentially result in decreased postoperative complications and associated costs**

#### Glove Powder and Extractable Protein

- Powdered gloves may cause adverse events and medical complications such as postoperative adhesions, granulomas, delayed wound healing, increased risk of infection and occupational asthma<sup>5</sup>
- Biogel is the only major surgical glove brand with an exclusively powder-free range
- Exceptionally low extractable protein levels
  - Biogel range typically <20µg/g
  - Biogel Eclipse® range typically <40µg/g<sup>6</sup>
- **Biogel gloves reduce the chance of latex allergy and postoperative complications**

#### Durability

- Biogel gloves exceed industry standards for<sup>1</sup>
  - Force at break
  - Tensile strength
  - Elongation

#### Biogel Preference

- 9 in 10 surgeons agree that Biogel gloves are high-quality and provide the durability they need throughout surgical procedures<sup>7</sup>
- Biogel coating makes damp donning easy – the world's first polymer coating with hydrophilic properties that conforms to the hand like a second skin
- Over 99.9% of Biogel inventory has been available at all times for the past 4+ years<sup>8</sup>
- Biogel receives an exceptionally low level of complaints – two complaints per million gloves sold<sup>9</sup>

**For safety, dependability and selection, there is only one choice.**



SETTING THE STANDARD IN PROTECTION



MÖLNLYCKE  
HEALTH CARE

Cardinal Health is a registered trademark of Cardinal Health Technologies, LLC.  
Medline is a registered trademark of Medline Industries, Inc.

Sempered is a registered trademark of Semperit Technische Produkte Gesellschaft M.B.H. Ltd.  
Ansell is a registered trademark of Ansell Limited Corporation.

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<sup>1</sup> MKT004 Why Choose Biogel.

<sup>2</sup> Mölnlycke Health Care Study #G09-005.

<sup>3</sup> Sharma, G., Gilson, M., Nathan, H., Makary, M.:

"Needlestick Injuries Among Medical Students: Incidence and Implications." *Academic Medicine*; Dec2009, Vol. 84 No. 12, p1815-1821.

<sup>4</sup> Dorland, W. (Ed.). (2003). *Dorland's Illustrated Medical Dictionary*. (30th ed.). (2003). Philadelphia, PA: Saunders.

<sup>5</sup> Truscott, W., "Citizen's Petition to the Food and Drug Administration to Ban Cornstarch Powder on Medical Gloves." Feb2009.

<sup>6</sup> Data on File. Mölnlycke Health Care. Report #647 9/29/2008.

<sup>7</sup> Data on File. Proprietary independent survey conducted spring 2008 among U.S. surgeons, OR managers/nurses and purchasing agents (total of 155 respondents) who were blinded to study sponsor.

<sup>8</sup> Data on File. Mölnlycke Health Care Logistics.

<sup>9</sup> Data on File. Mölnlycke Health Care.